



Department of Health

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April 23, 2010

Edward J. Markey, Chairman
Subcommittee on Energy and Environment
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6155

Dear Chairman Markey:


This letter is in response to your letter dated 18 March 2010 requesting information regarding Rhode Island's regulation of medical patients being treated and released with medical isotopes. Please note that the Rhode Island *Rules and Regulations for the Control of Radiation* [R23-1.3-RAD] can be found on the Rhode Island Secretary of State's regulations website at <http://sos.ri.gov/documents/archives/regdocs/released/pdf/DOH/4864.pdf>.

The RI program is determined to be adequate and compatible with the US Nuclear Regulatory Commission (NRC) requirements to protect public health and safety in Rhode Island.

The authority to regulate the safe use of radiation in Rhode Island is with the Office of Facilities Regulation - Radiological Health Program within the Rhode Island Department of Health. This program oversees the regulation of radioactive materials licensees & registrants, users of x-ray devices, and tanning.

If you need additional information or need further clarification, please do not hesitate to contact William Dundulis of my staff via phone at 401-222-7767 or email at Bill.Dundulis@health.ri.gov. Thank you for your letter and concern for the public.

Sincerely,



Raymond Riosin, Chief
Office of Facilities Regulation

Cc: David R. Gifford, MD, MPH, Director, RI Department of Health
Michael S. Varadian, JD, MBA, Executive Director, Environmental Health Services Regulation

1. *How many I-131 licensee facilities are overseen by your State?*

Response: RI currently has seven (7) licensees that are authorized to use Iodine 131 in therapeutic quantities (i.e., quantities that exceed thirty microcuries (30 μ Ci), and which require a written directive). However, only three (3) of these licensees are authorized to administer full I-131 therapy doses. The remainders of the licensees are limited to treatment of hyperthyroidism, which typically requires a dose of I-131 that is significantly less than the old NRC limit of thirty millicuries (30 mCi) referenced in your letter.

2. *How often does your State perform sampling inspections at each of these I-131 licensee facilities?*

Response: RI currently uses the same inspection frequency as NRC for a given type/category of license. Broad scope medical licenses [2 licensees] are inspected every two (2) years. Specific medical licensees who require use of a written directive [1 license] are inspected every three (3) years. [NOTE: The other four (4) licensees that are only authorized to use I-131 for treatment of hyperthyroidism would also be inspected every three (3) years.]

3. *What does such an inspection entail? Please provide copies of any handbooks or inspection checklists or other similar documents that are used to conduct such inspections.*

Response: RI follows all NRC applicable guidance outlined in Inspection Manual Chapter 2800 (IMC 2800), this includes the inspection criteria for a facility requiring written directives, including those facilities that administer I-131, in Inspection Procedure (IP) 87131 "Nuclear Medicine Programs, Written Directive Required". We have developed our own similar procedure, which is attached (Attachment 1). With respect to the release of patients, IP 87131 requires, in part, that the inspector determine by direct observations and, if needed, review of selected records that the licensee is knowledgeable about patient release criteria and is in compliance with the RI patient release criteria in §C.8.24 of the *Rules and Regulations for the Control of Radiation*. Inspectors also verify that the licensee's evaluation for release of the patient meets the requirements in §C.8.24. The inspectors review a sample of the licensee's written instructions to the patient to determine if the instructions meet current requirements.

4. *NCRP 155, includes "Radiation Safety Precautions for Radiopharmaceutical Therapy Patients". For a patient receiving 175 millicuries of I-131, the patient is instructed not to hold or embrace children for more than 10 minutes a day for 21 days; to refrain from sharing a bed with one's sleeping partner for 7 days; and for the first day, to store and launder one's used clothing and bed linens separately from the rest of the household, using two rinse cycles; to wipe down the telephone with paper towels and then discard the paper towels; etc. What instructions has your State given to its medical licensees about how to provide guidance to patients to ensure that these radiation precautions will be followed?*

Response: RI's dose limits and restrictions are required to be compatible with the NRC's. Although NRC has assigned a "C" compatibility to the patient release criteria (i.e., the manner in which the essential objectives are addressed need not be the same as NRC, provided the essential objectives are met), RI has adopted the same criteria as NRC and is not more restrictive. Appendix U to NUREG 1556-Volume 9 [Revision 2-January 2008] contains recommended protocols, although licensees can adopt equivalent procedures.

5. *In the past ten years, how many times has your State, as part of the inspections it conducts, requested documentation from the licensee facilities that details the individualized analysis and/or dose calculations used when determining whether to send a patient that was treated with I-131 in excess of the default limits home, or to a hotel?*

Response: As noted in RI's response to #3 above, our inspectors evaluate the licensee's patient release program to verify compliance with State of Rhode Island requirements [i.e., §C.8.24 of the *Rules and Regulations for the Control of Radiation*] during each inspection. This includes determining if the licensee is knowledgeable about release criteria, maintains appropriate records to document the basis for authorizing the individual's release, and provides adequate instructions to patients. Further on-site review of licensee documentation is only conducted if apparent deficiencies are noted. The inspector does typically not retain copies of documents reviewed during inspection unless these documents indicate a noncompliance with applicable regulatory requirements. RI does not maintain a specific record of how many times inspectors have reviewed such records during an inspection.

6. *In the past ten years, how many times has your State, as part of these inspections, requested documentation from the licensee facilities that details the guidance provided to the patient by the licensee facility when the patient is release from licensed care.*

Response: Although §C.8.24 of the *Rules and Regulations for the Control of Radiation* requires that a record of the basis for release of each patient be maintained, RI does not specifically require licensees to keep a copy of the specific instructions provided to each patients. However, most licensees have adopted a protocol that requires that a copy of the discharge instructions be signed by the patient, acknowledging the release conditions according to the instructions they are being given. During inspections, the inspector reviews a representative sample of cases for compliance. If the licensee does not keep copies of instructions for each patient or appropriate instruction models are not available at the licensee's facility, the inspector determines if the licensee is knowledgeable about release criteria and communicating adequate instructions to patients to determine if the licensee is in compliance with the regulations. RI does not maintain a specific record of how many times inspectors have reviewed such records during an inspection.

7. *In the past ten years, how many times has your State identified problems with the individualized analysis and/or dose calculations used or guidance provided to the patient by the licensee facility? Please detail these problems.*

Response: RI has not found any cases in which the licensee did not perform a required dose calculation or the licensee did not provide written instructions to the patient on how to maintain doses to other individuals as low as reasonably achievable (ALARA). In all cases reviewed, the licensee has demonstrated that the patients were allowed to be released per §C.8.24 of the *Rules and Regulations for the Control of Radiation*.

8. *In situations where an individualized analysis of dose to others is required, it would seem impossible for the authorizing physician to do so for a patient going to a hotel, since this would require a knowledge of the layout of the hotel and the proximity to the nearest other guest, who might be a child or a pregnant woman sleeping on the other side of a wall. Do you agree?*

Response: RI believes that a licensee is quite capable of calculating conservative dose estimates which utilize reasonable assumptions concerning occupancy, building geometry, and other factors. These instructions are explained to the patient prior to being discharged. However, as with all outpatient treatments, the discharge instructions can't possibly address (or control) what a patient does once they leave the licensed facility.

9. *Has your State ever attempted to determine how many patients treated with I-131 are a) sent home, b) sent to a hotel or c) kept in the hospital for additional time? If so, please provide the results. If not, why not?*

Response: RI does not require licensees to maintain records regarding the destinations of patients released from their facility. Either a patient can be safely discharged or they can't. As noted above, our inspectors review a representative sample of cases involving therapeutic uses of radioactive materials during on-site inspections at medical facilities. These reviews are used to verify compliance with §C.8.24 of the *Rules and Regulations for the Control of Radiation*, regardless of the patient's final destination.

10. *In patients with doses in excess of the default limits, has your State ever attempted to determine whether these I-131 licensee facilities always perform individualized analysis of each patient's living circumstances prior to releasing them? If not, why not? If so, has your State ever encountered situations when individual analyses and/or dose calculations were not performed when they were required? Please provide reports and documentation relating to these cases.*

Response: As discussed in our response to #7 above, RI inspectors have not identified any situations where the individualized dose calculation required by §C.8.24 of the *Rules and Regulations for the Control of Radiation* was not performed.

11. *What are the disclosure rules for patients who go to a hotel following treatment? Are licensees required to give patients explicit instructions to provide to hotel management?*

Response: As discussed in our response to #9 above, either a patient can be safely discharged or they can't. Therefore, RI does not require licensees to give patients explicit instructions to provide to hotel management. However, we do recommend that our licensees refer to the NRC's guidance for medical use licensees [Appendix U to NUREG 1556-Volume 9 (Revision 2-January 2008)] which contains general objectives, rather than prescriptive directions, for maintaining doses to other individuals ALARA. When NRC periodically reviews/updates this guidance document, RI makes the necessary revisions to our guidance document at that time.

12. *Has your State ever issued an advisory or guidance warning licensees not to send radioactive patients to hotels? If so, please provide copies.*

Response: RI has never issued any such advisory or guidance. However, we do routinely forward (to our licensees) any new or revised NRC guidance documents regarding medical use of radionuclides (both diagnostic and therapy).

13. *Are your licensees required to report to you instances in which released I-131 patients caused radiation exposure to family members or members of the public?*

Response: RI doesn't require such a report. Once a patient is released pursuant to §C.8.24 of the *Rules and Regulations for the Control of Radiation*, there are no further requirements for either the patient or the licensee.

14. *Please provide copies of all correspondence, including emails, letters, meeting or telephone notes or other materials, between your State and the NRC related to the release of patients that have been treated with radionuclides.*

Response: The only correspondence RI has is the routine review of our program through the Integrated Materials Performance Evaluation Program (IMPEP). These reports can be found on the NRC's website: <http://nrc-stp.ornl.gov/rulemaking.html#RI>.

15. *Please also provide reports for instances in which documents relating to patient release were found to be missing, inadequate, or unclear during the course of a sampling inspection. If your sampling inspections found that a licensee knew of a patient who went to a hotel after treatment, whether or not by explicit instruction, please provide all documentation relating to those cases.*

Response: If documents required pursuant to §C.8.24 of the *Rules and Regulations for the Control of Radiation* are missing or incomplete, then it would be considered a violation of RI requirements. If the documentation were initially unclear, the inspector would ask additional questions to determine if a violation had actually occurred. Consequently, any identified violation would be cited as such in the inspection report. There are no known cases where a RI licensee gave a discharged patient specific instruction to go to a hotel after I-131 therapy. As noted in our response #13 above, once a patient is properly released, there are no further requirements for either the patient or the licensee. Therefore, we have no way of determining if a discharged patient went to a hotel on their own.